

THE BELL RINGER

The Newsletter of the Philadelphia Conference of the Central Atlantic States
Association of Food and Drug Officials

Summer 2010



THE PRESIDENT'S MESSAGE

The "Gavel" has passed, and I am honored to serve as your President for the next two years. I would like to thank Dr. Palak Raval-Nelson for serving as President for the Philadelphia Conference for the past two years. In addition, we must recognize the Philadelphia Conference Board members and Educational Committee, who work faithfully and tirelessly to assure the very best training opportunities for our members. Additionally, we are grateful for our industry members, who have taken a more active role in supporting CASA. Also, we can't forget to congratulate Howard Rabinovitch, who was presented with this year's CASA Award at the Annual Conference in Hauppauge, NY. This prestigious award is well deserved, as Howard's involvement and contributions to CASA span over 40 years. CONGRATULATIONS HOWARD!!

This is a difficult economic time, and we are all facing cuts in our agencies and businesses, but, we are fortunate to have the dedication of the Philadelphia Conference members, some of whom take their own time to attend our meetings. It is evident by both the turn-out at our June training session, and the positive feedback that we received, that we are turning a new corner, and a very positive one at that! Education is one of the greatest tools for any profession, and CASA offers education and training to all of our members at a price we can afford. Please don't forget to register for our training meetings, with Lynn Bonner at: lynn.bonner@fda.hhs.gov and thank you Lynn, for your help any time I have asked for it. In addition, a special thanks to Jack Welte for his dedication to the training committee, and to Gloria Dougherty who applies for the CEU's for our New Jersey members.

We will continue to collect food for the needy at our training sessions thanks to Patricia Taylor! She has coordinated this special program and does an outstanding job for this worthy cause. The following items are always needed; Juice/drink mixes, tuna, peanut butter& jelly, jello & pudding, hamburger helper, rice, pancake mix, syrup, paper products-toilet paper, paper towels, tissues, condiments, ketchup, mustard, mayonnaise, Toiletries, soap tooth paste shampoo, deodorant.

We look forward to seeing you at our next training meeting on Friday, September 10, 2010, at the Camden County Fire Academy Training Center.

Sincerely,
Mary Beck
President, Philadelphia Conference



FDA NEWS RELEASE

For Immediate Release: June 1, 2010

Media Inquiries: Elaine Gansz Bobo, 301.796.7567, elaine.bobo@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Approves New Injectable Osteoporosis Treatment for Postmenopausal Women

The U.S. Food and Drug Administration today approved Prolia, an injectable treatment for postmenopausal women with osteoporosis who are at high risk for fractures.

Osteoporosis is a disease in which the bones become weak and are more likely to break. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, 80 percent of the people in the United States with osteoporosis are women. One out of every two women over age 50 will break a bone in their lifetime due to osteoporosis.

People with osteoporosis at high risk for fracture include those that have had an osteoporotic fracture, or have multiple risk factors for fracture; or those who have failed or are intolerant to other available osteoporosis therapy. Prolia works to decrease the destruction of bone and increase bone mass and strength. An injection of Prolia is recommended once every six months.

“Due to its prevalence, osteoporosis is a serious concern to public health,” said Julie Beitz, M.D., director of the FDA’s Office of Drug Evaluation III. “The approval of Prolia provides another treatment option for postmenopausal women with osteoporosis who are susceptible to fractures.”

The safety and efficacy of Prolia in the treatment of postmenopausal osteoporosis was demonstrated in a three-year, randomized, double-blind, placebo-controlled trial of 7,808 postmenopausal women ages 60 to 91 years. In the study, Prolia reduced the incidence of vertebral, non-vertebral, and hip fractures in postmenopausal women with osteoporosis.

The most common side effects reported with Prolia include back pain, pain in the extremities, musculoskeletal pain, high cholesterol levels, and urinary bladder infections. Serious adverse reactions include hypocalcaemia (low calcium levels in the blood), serious infections, including infections of the skin, and dermatologic reactions such as dermatitis, rashes, and eczema.

Prolia causes significant suppression of bone turnover and this suppression may contribute to the occurrence of osteonecrosis of the jaw, a severe bone disease that affects the jaw, atypical fractures, and delayed fracture healing.

Prolia was approved with a risk evaluation and mitigation strategy (REMS) that includes a Medication Guide for patients and communications to health care providers that explains the risks and benefits of the drug.

Prolia is manufactured by Amgen Manufacturing Limited, a subsidiary of Thousand Oaks, Calif.-based Amgen Inc.

For more information

[Fast Facts on Osteoporosis – National Institute of Arthritis and Musculoskeletal and Skin Diseases](#)
[RSS Feed for FDA News Releases](#)

FDA NEWS RELEASE

For Immediate Release: May 24, 2010

Media Inquiries: Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Clears First 2009 H1N1 Influenza Virus Test Previously Available Under Emergency Use Authorization

Clearance will allow continued use of Simplexa Influenza A H1N1 (2009) test

The U.S. Food and Drug Administration today announced it has cleared the Simplexa Influenza A H1N1 (2009), a test for the 2009 H1N1 Influenza Virus in patients with signs and symptoms of respiratory infection.

Until this clearance, tests for 2009 H1N1 Influenza were only available through an Emergency Use Authorization (EUA), which allows the FDA, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products, during the time a declaration of emergency is in effect.

On April 26, 2009, the U.S. Department of Health and Human Services declared a public health emergency due to the 2009 H1N1 Influenza Virus. EUAs for devices will cease to be effective when the public health emergency declaration expires.

“With this clearance, the availability of Simplexa H1N1 test will not be affected when the public health

emergency expires,” said Jeffrey Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health.

Using specimens from nasal swabs or nasal aspirates, the Simplexa Influenza A H1N1 (2009) test simultaneously amplifies and detects two regions of the influenza virus genome and an internal control. A positive result indicates that the patient is infected with the 2009 H1N1 influenza virus, but the test does not indicate the stage of infection. A negative result does not preclude influenza virus infection.

The United States experienced its first wave of 2009 H1N1 Influenza Virus in the spring of 2009, followed by a second wave in the fall. The U.S. Centers for Disease Control and Prevention estimates that between 43 million and 88 million cases of 2009 H1N1 occurred between April 2009 and March 13, 2010.

The Simplexa Influenza A H1N1 (2009) test is manufactured by Focus Diagnostics Inc. in Cypress, Calif.

For more information

- [FDA 2009 H1N1 Influenza Virus web site](#)
- [CDC 2009 H1N1 Flu Virus web site](#)

FDA PRESS RELEASE

For Immediate Release: May 24, 2010

Media Inquiries: Pat El-Hinnawy, 301.796.4763, patricia.el-hinnawy@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA and NIH Launch Electronic Safety Reporting Portal

The Food and Drug Administration and the National Institutes of Health today launched a new Web site that, when fully developed, will provide a mechanism for the reporting of pre- and post-market safety data to the federal government. Currently the Web site can be used to report safety problems related to foods, including animal feed, and animal drugs, as well as adverse events occurring on human gene transfer trials. Consumers can also use the site to report problems with pet foods and pet treats.

The new site, called the Safety Reporting Portal (SRP), provides greater and easier access to online reporting.

“The portal will be a key detection tool in improving the country’s nationwide surveillance system and will strengthen our ability to protect the nation’s health,” said Commissioner of Food and Drugs Margaret A. Hamburg. “We will now be able to analyze human and animal safety-related events more quickly and identify those measures needed to protect the public.”

The new Web portal includes different features for different types of reporting:

- **Reportable Food Registry:** Industry will have a more user-friendly electronic portal for submitting reportable food reports that are required by law. This electronic portal collects reports from the food industry and public health officials regarding problems with articles of food, including animal feed, that present a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- **Pets:** Pet owners and veterinarians will be able to use the portal to report product problems with pet foods and pet treats.
- **Animal drugs:** Animal drug manufacturers can report adverse drug events associated with animal drugs.
- **Clinical Trials:** Biomedical researchers involved in human gene transfer clinical trials can report an adverse event, indicating whether it might be an unanticipated consequence of the product being tested. Trial sponsors can use the portal to prepare a report, print it and send it to the agency to satisfy reporting requirements for investigational new drugs.

In the future, the system will encompass other types of clinical trials and, eventually, safety problems arising from products regulated by a broad array of federal agencies. This is a first step toward a common electronic reporting system that will offer one-stop shopping, allowing an individual to file a single report to multiple agencies that may have an interest in the event.

Just as important, the portal will ultimately enhance the government’s systematic analysis of safety information, which will benefit public health. In the meantime, the new portal redirects individuals who want to submit reports about other products regulated by FDA, the U.S. Department of Agriculture, Environmental Protection Agency or the Consumer

Product Safety Commission to the appropriate contact.

For more information

- [Safety Reporting Portal](#)
- [FDA Safety Reporting](#)
- [Reportable Food Registry for Industry](#)
- [Reporting a Problem with Veterinary Products](#)

FDA PRESS RELEASE

For Immediate Release: May 12, 2010

Media Inquiries: Shelly Burgess, 301-796-4651, shelly.burgess@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA: Serious Side Effects from Swallowing Topical Benadryl Product

The U.S. Food and Drug Administration is warning consumers about potentially serious side effects from mistakenly swallowing Benadryl Extra Strength Itch Stopping Gel, an over-the-counter (OTC) product that should only be used on the skin.

The FDA has received reports of serious side effects in people who have mistakenly swallowed the product. Some OTC Benadryl products are intended to be swallowed. However, Benadryl Extra Strength Itch Stopping Gel is only safe and effective when used, as directed, on the skin. People swallowing the gel can ingest a dangerous amount of the active ingredient, diphenhydramine. Large doses of diphenhydramine can result in serious side effects such as unconsciousness, hallucinations, and confusion.

“Consumer confusion and incorrect product use are serious public health issues,” said Carol Holquist, R.Ph., director of FDA’s Division of Medication Error Prevention and Analysis. “FDA is advising consumers and pharmacies to store products for the skin separately from products that should be swallowed.”

Many pharmacies and grocery stores sell diphenhydramine topical gels that look very similar in packaging to Benadryl Extra Strength Itch Stopping Gel. It is important that consumers also avoid swallowing these products.

To help consumers recognize that Benadryl Extra Strength Itch Stopping Gels meant for use on the

skin, the manufacturer, Johnson and Johnson, has taken the following actions:

- Changed the product label to add a new, prominent statement “For Skin Use Only.”
- Attached a sticker to the cap of the product that says “For Skin Use Only.”
- Initiated consumer studies to better understand factors that may contribute to consumers mistakenly swallowing Benadryl Extra Strength Itch Stopping Gel.

The FDA encourages manufacturers of similar products to adopt similar changes to their labeling and packaging.

The repackaged product is currently stocked in retail stores. The FDA reminds consumers and health care professionals to always read the “Drug Facts” box to identify active ingredients, directions for use, and warnings before using any OTC drug product.

Consumers and health care professionals are encouraged to report adverse side effects to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch¹ or by calling 800-332-1088.

For more information:

[FDA 101: Medication Errors](#)

FDA News Release

For Immediate Release: May 10, 2010

Media Inquiries: Michael Herndon 301-796-4673, Michael.Herndon@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

Minor edits were made to this document on May 11, 2010 to provide additional clarification

Federal and State Officials Confirm Link Between Bagged Romaine Lettuce and *E. coli* O145 Illness Outbreak

The Food and Drug Administration (FDA), with the Centers for Disease Control and Prevention (CDC) and its state health partners have confirmed that the strain of *E. coli* O145 detected by the New York State Public Health Laboratory, Wadsworth Center, in Albany, in an unopened bag of shredded romaine lettuce distributed by Freshway Foods, matches the outbreak strain of *E. coli* O145.

This finding comes as federal and state public health officials continue to investigate the foodborne illness outbreak linked to certain romaine lettuce products sold to wholesalers and food service outlets.

To date, there have been 19 confirmed and additional unconfirmed cases of *E. coli* O145 infections in Michigan, Ohio, and New York. These illnesses include 12 individuals who have been hospitalized, and three with a potentially life threatening complication called hemolytic uremic syndrome (HUS). HUS is a serious condition in which the body's blood-clotting mechanisms are altered, causing blocked circulation or bleeding in the brain or kidneys.

Last week, [Freshway Foods of Sidney, Ohio](#)¹, voluntarily recalled certain romaine lettuce products because of the possible connection to the *E. coli* O145 foodborne illness outbreak. The recalled shredded romaine lettuce had "best if used by" dates of May 12 or earlier.

Federal and state investigators are attempting to determine the point in the supply chain where the contamination occurred. Investigations are in progress at the Freshway Foods processing facility and at a farm in Yuma, Arizona which grew the romaine lettuce supplied to Freshway Foods during the time period of interest.

Andrew Smith, Co., a Salinas, California-based grower-shipper who distributed the lettuce from the farm in Yuma, has contacted its customers to recall any lettuce originating from the farm. Vaughan Foods of Moore, Oklahoma, a supplier of processed and packaged lettuce for restaurants and other foodservice facilities, received romaine lettuce grown on the Yuma farm from Andrew Smith, Co. and is recalling romaine lettuce with "use-by" dates of May 9 and May 10. The recalled romaine lettuce distributed by Vaughan Foods was not available for purchase at retail by consumers. To date, no known illnesses have been associated with the romaine lettuce distributed by Vaughan Foods. According to records from Andrew Smith Co., no other consignees had romaine from this farm still in commerce. Lettuce harvested from other geographic areas does not appear to be associated with this outbreak.

Symptoms of infection with harmful *E. coli* may range from none to mild diarrhea to severe complications. The acute symptoms include severe abdominal cramps and diarrhea, which may be bloody. Patients may progress to serious complications, such as kidney damage. The FDA and CDC encourage anyone who has experienced the

symptoms following ingestion of romaine lettuce products described here to contact his or her health care provider immediately.

For more information:

- On this outbreak of *E. coli* O145 see: <http://www.cdc.gov/ecoli/>².
- On foodborne illness visit foodsafety.gov³.
- [See previous FDA news releases on this topic](#).⁴

FDA NEWS RELEASE

For Immediate Release: March 26, 2010

Media Inquiries: Ira Allen, 301-796-5349;

ira.allen@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Takes Action Against New York Dairy Farmer

Proprietor sold animals with illegal drug residues in violation of federal law

A New York State dairy farmer cited by the U.S. Food and Drug Administration for selling cows that had illegal residues of antibiotics was ordered by the U.S. District Court for the Western District of New York this week to stop offering the animals for slaughter until he complies with federal law.

Federal Judge Richard J. Arcara entered a consent decree of permanent injunction on March 25 against Jerald P. Schumacher, the sole proprietor of a farm in Wyoming, N.Y., which sells its dairy cattle to an auction yard in Pavilion, N.Y., to be slaughtered for human consumption.

The FDA complaint said Schumacher has sold cows for slaughter for at least 10 years with residues of the antibiotics penicillin and sulfadimethoxine in the animals' edible tissue. The agency also said he illegally gave the cows higher-than-allowed dosages.

"The sale of animals for animal-derived human food products that contain illegal levels of animal drugs poses a significant public health risk," said Bernadette Dunham, D.V.M., Ph.D, director of FDA's Center for Veterinary Medicine. "FDA will continue to take action against producers who violate federal laws intended to protect the health of the public and of livestock."

The farm was most recently inspected between Oct. 6 and Oct. 21, 2009, and Schumacher was given a

written report detailing the violations. After FDA issued a warning letter in 2006 requiring him to abide by the law, violations continued.

The U.S. Department of Agriculture, which has the responsibility for detecting drug residues in beef sold for human consumption, cited Schumacher six times in the past 10 years.

Schumacher also violated the law by failing to keep adequate records of which cows were medicated, according to the complaint.

For more information:

FDA's Electronic Reading Room-[Warning Letters](#)

[RSS Feed for FDA News Releases](#)

FDA NEWS RELEASE

For Immediate Release: March 27, 2010

Media Inquiries: Rita Chappelle, 301-796-4672 or 240-753-8603, rita.chappelle@fda.hhs.gov

Trade Inquiries: Stephanie Kwisnek, 301-436-1856, stephanie.kwisnek@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

Public Health Agencies Collaborate to Prevent Further Illnesses from Norovirus Outbreak Associated with Oysters Recently Harvested from Area Near Port Sulphur, La.

The U.S. Food and Drug Administration is working with state health officials from Mississippi and Louisiana to notify consumers, food service operators and retailers nationwide about an outbreak of norovirus associated with oysters recently harvested from an area near Port Sulphur, La. known as Area 7. The oysters were sold or distributed nationwide.

Public health agencies are warning consumers not to purchase or eat oysters from the affected area and warning retailers and food-service operators not to sell or serve them. Louisiana's Area 7 is in the Gulf of Mexico near the mouth of the Mississippi River.

The FDA was notified by state authorities that nearly a dozen consumers in Mississippi fell ill with norovirus after eating raw oysters from the affected area on March 10. Norovirus is a foodborne pathogen that can cause acute gastroenteritis in humans.

The Louisiana Department of Health and Hospitals has recalled oysters harvested from Area 7 on March 6 through March 24, 2010. State health officials closed the area to harvesting on March 24 to protect the public health.

Public health officials are currently working to investigate potential sources of pollution that may have caused the area to become contaminated.

Consumers who are uncertain about the origin of oysters they have in their possession should contact the place of purchase to determine if the oysters are from the affected area. Retailers and food service operators can check the tag or labeling that should accompany all raw molluscan shellfish to verify their origin.

Eleven people reported becoming sick after eating raw oysters at a conference center in Jackson County, Miss. Test results by the Mississippi State Department of Health confirmed that the patients were infected with norovirus.

Symptoms of norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people also have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms lasting for one or two days.

People who have eaten raw oysters harvested from the affected area during the specified dates and have had symptoms of norovirus infection are encouraged to contact their health care professionals and local health departments.

People with weak immune systems, including those affected by AIDS, chronic alcohol abuse, liver, stomach or blood disorders, cancer, diabetes, or kidney disease and those taking certain medications for rheumatoid arthritis or cancer chemotherapy, should avoid raw oyster consumption altogether, regardless of where the oysters are harvested.

For more information on seafood safety, please visit:

<http://www.cfsan.fda.gov/seafood1.html> or call FDA's Food Safety Hotline at 1-888-SAFEFOOD.

For information on Norovirus, go to:

http://www.foodsafety.gov/poisoning/causes/bacteria_viruses/norovirus.html²

For additional information on seafood, go to:

<http://www.foodsafety.gov/keep/types/seafood/index.html>

[RSS Feed for FDA News Releases](#)

From the Editor

It's Summer Time!!!! Break out the swimming trunks and fire up the grill. Make sure you get out and enjoy the many special events the City of Philadelphia and its surrounding areas has to offer.

The next training meeting is right around the corner (**September 10th - Blackwood, NJ**). Jack Welte, our Education Committee Chair, is looking for new training topics. We need to know your interests, ideas and concerns to assist us in the development and implementation of new training sessions which cover topics that you feel are pertinent. I encourage you to take an active role in our organization.

Do you have information that needs to be heard? If you have a story idea, an announcement, or information, please email it to me at Rodney.rice@phila.gov. Also, feel free to provide feedback on the articles in the issues or write a letter to the Editor. Lastly, space is available for advertising in the Bell Ringer, simply send me the information in an email and I will contact you. I look forward to your feedback and participation. Enjoy the Holiday Season.

Rodney D. Rice, MBA



CASA Upcoming Training Meetings

"Dues will be accepted"

Fall Meeting
Winter Meeting

September 17, 2010
December 10, 2010

Make sure to
register your email
on the CASA
website:
[http://www.casafdo.
org/](http://www.casafdo.org/)

Would you really like to make an
impact?!?!
How about running for The
Representative to the
Executive Board of Mama
CASA
Election will be held this March...